

## Health Legislation and Policy

The process by which U.S. federal legislation affecting the health industries is enacted is complex and often counterintuitive. That is why effective participation in the legislative process often requires hands-on experience on Capitol Hill and in the administrative agencies, in addition to in-depth knowledge of health care services and delivery. With a practice that includes a former member of the U.S. Congress, numerous former congressional and agency senior staff, and significant experience in health care-related law and business, we help clients navigate their way through the labyrinth by which federal law and policy are established.

On issues such as regulation of the pharmaceutical and biotechnology industries, Medicare and Medicaid reform, requirements and restrictions involving clinical research, medical liability, long-term care, public health, and patient privacy, we work with clients to construct and carry out strategies for communicating their point of view and participating in the legislative and administrative processes by which federal laws are enacted and policies are established. We are bipartisan in our approach, maintaining strong relationships with lawmakers and committee staff on both sides of the aisle, and regulatory officials in both Republican and Democratic administrations. On Capitol Hill and in the agencies, our lawyers are respected for their deep knowledge of health law and policy, their experience

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### Practices

Government Relations  
and Public Affairs

Health

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with legislative and administrative processes, and their ability to clearly and effectively advocate in that context on their clients' behalf.

Often clients rely on us to augment their in-house government relations capabilities by keeping them informed of developments and helping them understand the genesis and likely effects. For a number of clients, we closely watch health-related legislation and regulatory activity, draft comments on proposed rules, and provide regular updates. For health care associations, we provide representation in the U.S. Congress on legislative matters and before executive agencies on regulatory and rulemaking issues. For example, as Congress worked to write new Medicare prescription drug legislation, we worked with several clients to include language vital to their businesses.

## Representative experience

Secured US\$10m in Title VII funding for pediatric dentistry residency and loan repayment programs on behalf of the American Academy of Pediatric Dentistry.

Assist a client in obtaining funding for eye and vision research in the defense appropriations bill resulting in over US\$20m in the last six fiscal years.

Worked with leading research institutions, major industry associations, key House and Senate leaders, and the administration to secure a positive CMS coverage determination for bone-anchored hearing devices.

Represented pharmaceutical and biologics companies in connection with numerous federal and state investigations of sales and marketing, pricing, Medicaid rebate, FDCA promotional issues, and cGMP compliance.

Advised a drug company on strategies for obtaining orphan drug approval and worked with scientific and regulatory groups to draft and submit designation request.

Lobbied Congress on behalf of Insulet to get CMS approval for an insulin delivery product.

Succeeded in working with a national health professional organization to secure over US\$10m in direct funding for specific health professional training and loan guarantees.

Worked with several corporations and industry associations to secure critical appropriations report language supporting access and reimbursement for specific medical technologies.

Advised a U.S. medical device company on regulatory and commercial issues regarding the market launch of a gene test in 24 European countries.

Instrumental in persuading the FDA to change longstanding regulatory position on awarding exclusivity to fixed-dose combination products, benefitting Gilead's products in the HIV and Hepatitis C fields.

Lead agency counsel for implementation of Affordable Care Act, including provisions governing health insurance coverage and Medicare Advantage plans.

## Latest thinking and events

### Hogan Lovells Events

Health Care AI Law and Policy Summit

### Hogan Lovells Events

WTO IP rights: The future of products combating COVID-19

### Published Works

2021 Chambers Global Practice Guide in Life Sciences  
*Chambers Global Practice Guide*

### Hogan Lovells Publications

First courts consider application of PREP Act Immunity in the context of removal

### Webinar

Buy American panel discussion: How will this month's Executive Order impact drug and device companies, and what should you do about it?

## Blog Post

COVID-19: African unity and the opportunity for a paradigm shift